

**REMARKS**

Applicant thanks the Examiner for taking the time on January 11 and 16, 2007, to discuss the previous Office Action and the requirement for election/restriction. Applicant confirms the election, with traverse, of species I, claims 85-113. Non-elected claims 114-152 are cancelled, without prejudice, by the present amendment and will be presented for examination in a divisional application.

Reconsideration of the rejections set forth in the Office Action dated January 22, 2007, is respectfully requested. Claims 92, 107, and 114-152 have been cancelled, without prejudice, in view of the requirement for election/restriction. Claims 85 and 99 have been amended. The amendments were described in previously pending claims 92 and 107, in the specification, e.g., at Figs. 2, 9A, 9B, 11A, 14A, and in the description of these figures. These amendments are therefore made without introducing new matter.

**Double Patenting Rejection**

Claims 85-113 were rejected for alleged obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,245,107. Without conceding the propriety of the rejection, Applicant submits herewith a terminal disclaimer. Therefore the rejection for alleged obviousness-type double patenting should be withdrawn.

**Art Rejection**

Claims 85-113 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Bao in view of Flament. This rejection should be withdrawn for the following reasons.

Claim 85 is limited to the step of “*expanding the porous mesh to a diameter larger than the defect, wherein the porous mesh expands radially by reducing the length between the distal and*

*proximal ends.” Claim 99 is limited to the step of “expanding the implant to a diameter larger than the defect, wherein the implant expands radially by reducing the length between the distal and proximal ends.” As acknowledged by the Examiner, Bao (USP 6,224,630) does not teach or suggest an implant or porous mesh that “expands radially by reducing the length between the distal and proximal ends.”*

Meanwhile, Flament teaches methods and devices for treating abdominal hernias, not intervertebral disc herniation. In order to explain the significance of this distinction and why one skilled in the art would dismiss Flament as inapplicable, Applicant submits herewith the Second Declaration of Bret Ferree, M.D., a Board Certified orthopedic surgeon who specializes in spinal surgery. Dr. Ferree has performed over 1,500 surgeries to repair intervertebral disc herniation and is therefore familiar with the types of devices that can and cannot be used to repair defects in the annulus fibrosis. Ferree 2<sup>nd</sup> Decl., ¶ 1. As explained by Dr. Ferree, intervertebral disc hernia repair raises entirely different considerations of anatomy, tissue healing, and biomechanics when compared with abdominal or inguinal hernia repair. Ferree 2<sup>nd</sup> Decl., ¶ 4. The design criteria are different for intervertebral disc devices such that spine surgeons would reject approaches designed for inguinal hernia repair as inapplicable. Ferree 2<sup>nd</sup> Decl., ¶ 4.

Moreover, Claim 85 is now limited to the step of “*expanding the porous mesh to a diameter larger than the defect, wherein . . . the proximal end of the porous mesh is located distally beyond the outer layer of the annulus fibrosis.*” Claim 99 is limited to the step of “*expanding the implant to a diameter larger than the defect, wherein . . . the proximal end of the implant is located distally beyond the outer layer of the annulus fibrosis.*” The claim language therefore excludes a device that extends outwardly beyond the outermost layer of the annulus toward the nerves. Thus, even if

combined, the cited references do not teach or suggest the claimed invention because Flament does not locate the proximal end of his implant distally beyond the outer layer of the annulus fibrosis. Ferree 2<sup>nd</sup> Decl., ¶¶ 5, 6. Further, those skilled in the art would not modify the position of Flament's device as suggested in the Office Action. Ferree 2<sup>nd</sup> Decl., ¶ 6. Flament requires sutures on the base of his conical implant to secure it to the abdominal wall. Ferree 2<sup>nd</sup> Decl., ¶ 6. Because of very limited space to access an intervertebral disc hernia and difficulties with applying sutures in such space, those skilled in spine surgery would understand that Flament's device cannot be located distally beyond the outer layer of the annulus fibrosis because of inability to suture within this space. Ferree 2<sup>nd</sup> Decl., ¶ 7, 8, 9, 10. Because Flament's device and technique require placement of at least a portion of the implant proximal the outer layer of the annulus fibrosis, the proposed combination of references, even if made, would not produce the claimed invention.

The proposed combination would also be rejected as inoperative or even dangerous by those skilled in the art. Given that intradiscal pressures typically exceed 750 mmHg, far above intra-abdominal pressures (150 mmHg), Flament's device would be forced out of the annulus fibrosis into the spinal canal if used as proposed in the Office Action. Ferree 2<sup>nd</sup> Decl., ¶¶ 11, 12. Placing sutures directly into the walls of annulus fibrosis near the defect is also highly problematic for a number of reasons. The sutures will tear away from the tissue, the implant will tear from the sutures, the knots will slip, or the implant will simply deform under pressures that exceed the limits of Flament's design, all resulting in the implant extending proximally beyond the outer layer of the annulus fibrosis and protruding into the spinal nerves. Ferree 2<sup>nd</sup> Decl., ¶¶ 13, 14. Given high intradiscal pressures, catastrophic failure resulting in extrusion of the entire Flament implant is also a likely outcome that would result in severe pain and possibly permanent nerve damage. Ferree 2<sup>nd</sup>

Decl.; ¶¶ 15, 16, 17, 18. Given the severe consequences of damage to nerve tissue when it contacts mesh, spine surgeons would reject the proposed use of Flament's device for treating herniated intervertebral discs. Ferree 2<sup>nd</sup> Decl., ¶¶ 19, 20.

Therefore, claims 85 and 99 are patentably distinct from Flament and Bao. Claims 86-91 and 93-98 depend from claim 85 and are therefore patentably distinct from Flament and Bao for the same reasons applicable to claim 85. Claims 100-106 and 108-113 depend from claim 99 and are thus patentably distinct from Flament and Bao for the same reasons applicable to claim 99. The art rejections should therefore be withdrawn.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,

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